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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,238	07/19/2001	Gerd Hobom	100725-10	8656

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NEW YORK, NY 10022

EXAMINER

MCGAW, MICHAEL M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,238

Applicant(s)

HOBOM ET AL.

Examiner

Michael M. McGaw

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 2-4, 6-8, 12-16, 19-21, 23-25, 27 and 30-35 is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claim Objections

Claims 4, 6, 7, 12-16, 19-21, 23-25, 27 and 30-35 objected to under 37

CFR 1.75(c) as being in improper form because a multiple dependent claim (1) may refer to another claim in the alternative only; and (2) a multiple dependent claim may not serve as a basis for any other multiple dependent claim, either directly or indirectly. See MPEP § 608.01(n). Appropriate correction is required.

Claims 3, 6, 20, 21, 30, 34 are objected to because of the following informalities: Each of these claims uses the word “preferably” within the text of the claim. Such usage creates ambiguity within the language of the claim because it is not clear if Applicant means to create a limitation to the claim using the text following the word preferably or is merely describing a preferred embodiment. Appropriate correction is required.

Claims 8, 14, 15 and 30 are objected to because of the following informalities: Each of these claims uses the word(s) “and/or” within the text of the claim. Such usage creates ambiguity within the language of the claim because it is not clear exactly which limitations Applicant intends for the claim. Appropriate correction is required.

Claim 2 is objected to because of the following informalities: Each of these claims uses the word(s) “or vice versa” within the text of the claim. Such usage creates ambiguity within the language of the claim because it is not clear exactly which limitations Applicant intends for the claim. Appropriate correction is required.

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The aforementioned objections will result in rejections under 35 U.S.C. 112 in subsequent Office Actions if not corrected in response to the present Restriction Requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18 and 20 drawn to a recombinant influenza virus, classified in class 424, subclass 206.1.
- II. Claim 19, drawn to a method for the production of recombinant influenza virus, classified in class 424, subclass 206.1.
- III. Claims 28-29, drawn to a method for the production of proteins utilizing a recombinant influenza virus, classified in class 530, subclass 350.
- IV. Claim 30, drawn to a method for preventing influenza, classified in class 424, subclass 206.1.
- V. Claim 31, drawn to a method for somatic gene therapy, classified in class 424, subclass 93.1.
- VI. Claim 32, drawn to a method for the transfer and expression of foreign genes into cells, classified in class 514, subclass 44.
- VII. Claim 34, drawn to a method for immunotherapy using ex vivo infected immune cells, classified in class 424, subclass 93.1.
- VIII. Claim 35, drawn to a method for the induction of antibodies, classified in class 424, subclass 206.1.

Claims 21-27 and 33 involve "use" claims which are considered nonstatutory under U.S. practice. It is unclear how to interpret these claims. Applicant is encouraged to re-draft the claims in accordance with U.S. practice and, where applicable, to suggest their inclusion within the appropriate grouping above or within separate groupings.

Inventions I and II-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in a myriad of methods including methods for producing proteins of interest or recombinant viruses in cell culture systems, such as the methods of Group II-III, and the recombinant virus could also be used in methods of use as a bio-affecting compound, either in vivo or ex vivo, as variously described in Groups IV-VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or

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method steps, restriction for examination purposes as indicated is proper. MPEP

803.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael M. McGaw whose telephone number is (571) 272-2902. The examiner can normally be reached on Monday through Friday from 8 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

m.m.

Friday, November 26, 2004

James C. Housel
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
11/29/04